DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GPC Medical Limited
Vikas Narang
Director-Exports
Plot Number 8, Shubh Plaza
M-Block DDA LSC, Vikas Puri
New Delhi, 110018
INDIA

September 30, 2015

Re: K143245
Trade/Device Name: GPC Intramedullary Nailing Systems
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB, JDS
Dated: July 30, 2015
Received: August 4, 2015

Dear Mr. Narang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 ); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143245

Device Name
GPC Intramedullary Nailing System

Indications for Use *(Describe)*
1. Indication for Use: Multi Angle Tibial Nail : The multi angle tibial nail is intended to stabilize fracture of the proximal & distal tibia and the tibial shaft, open and closed tibial shaft fractures, certain pre and post isthmic fractures and tibial malunions & nonunions.

2. Indications for Use: Ga-mma Nails: The Ga-mma Nail is indicated for use in stabilizing various types of intertrochanteric fractures of proximal femur.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

GPC Medical Ltd.
Govt. of India Recognized Star Export House

The Best Name in India in its field
Backed by experience since 1930
ISO 9001:2008 Certified
ISO 13485:2003 Certified
WHO-GMP Compliant
US FDA 510 (k)

## 510(k) Summary of Safety and Effectiveness

**(A.1)**
General Company Information

**Submitter's Name:** GPC Medical Limited
**Address:** Plot Number 8, Shubh Plaza, M Block, DDA LSC, Vikas Puri, New Delhi 110018, India

**Contact Person:** Mr. Vikas Narang

**Telephone Number**: +91-11-43222600 (100 Lines)

**Dated:** 27-10-2014

**Device Name:** GPC Intramedullary Nailing Systems

**Product Code:** HSB – Primary Code
JDS – Secondary Code

**Classification:** Class II

**Regulation Number:** 21CFR 888.3020 Intramedullary Fixation Rod

**A.2:**
**Proprietary Name:** GPC Intramedullary Nailing Systems

**Common or Usual Name:** Intramedullary Nail

**Classification Name:** Nail, Fixation, Bone

**Models:**

| S. No. | Specific Device Model Type |
|---|---|
| 01 | Multi Angle Tibial Nail |
| 02 | Ga-mma Nail |

Further for the fixation of GPC intramedullary nailing systems, there are locking bolts, and end caps that are used during surgical procedure for fixation of these devices in the fractured bones.

Following are the corresponding locking bolts and end caps.
Locking Bolts for Multi Angle Tibial Nail
End Cap for Multi Angle Tibial Nail

Lag Screw for Ga-mma Nail
Locking Screw for Ga-mma Nail
Set Screw for Ga-mma Nail
End Cap for Ga-mma Nail

**Available Sizes:**
Multi Angle Tibial Nail: 260mm to 360mm with 20mm interval between adjacent sizes.

Ga-mma Nail: single size of 180mm

A 3) IDENTIFICATION OF THE PREDICATE DEVICE:

Following are the predicate device 510(k) with which we are declaring substantial equivalence:

| S. No. | Name of Device | Manufacturer (Predicate Device | 510(k) number | GPC Device Name | Remarks |
|---|---|---|---|---|---|
| 01 | Tibial Nail System Ex | Synthes (USA) | K040762 | GPC Multi Angle Tibial Nail | |
| 02 | Gamma Nail | Howmedica Inc. | K972813 | GPC Ga-mma Nail | The Howmedica Inc.'s Gamma Locking Nail is now available as Stryker's Gamma Locking Nail, however the 510(k) is still available in US FDA database as that of Howmedica Inc. |

GPC Medical Ltd.
Govt. of India Recognized Star Export House

The Best Name in India in its field
Backed by experience since 1930
ISO 9001:2008 Certified
ISO 13485:2003 Certified
WHO-GMP Compliant
US FDA 510 (k)

**A 4).** Device Description: GPC Intramedullary Nailing Systems:

The GPC Intramedullary Nailing Systems include intramedullary nails and corresponding screws/end caps/locking bolts for fastening these intramedullary nails to the fractured bones.

**A 5)** Indications for Use:

1. Indication for Use: **Multi Angle Tibial Nail**

The Multi Angle Tibial Nail is intended to stabilize fracture of the proximal & distal tibia and the tibial shaft, open and closed tibial shaft fractures, certain pre and post isthmic fractures and tibial malunions & nonunions

2. Indications for Use: **Ga-mma Nails**

The Ga-mma Nail is indicated for use in stabilizing various types of intertrochanteric fractures of proximal femur.

1. Associated materials of construction: NIL
2. Identification of colour additives present (if any): NIL
3. Contact classification of the devices as per ISO 10993-1:2009 standard: Surgically Invasive, Long-Term, Implantable Devices in connection with tissue and bone.

A 6). Summary of Technological Characteristics as compared to the predicate devices:
SUBSTANTIAL EQUIVALENCE INCLUDING COMPARISON WITH PREDICATE DEVICES

A comparison between GPC Intramedullary Nailing Systems and predicate devices has been performed which has resulted in demonstration of equivalence in dimensional and performance criteria. Despite some dimensional variation, the equivalence has been demonstrated by performance bench testing of both subject and predicate devices.

**Following is the summary of parameters in which the comparison has been verified:**
**Multi Angle Tibial Nail versus Predicate Device**

| S. No. | CHARACTERISTICS | PREDICATE DEVICE VERSUS NEW DEVICE (GPC Intramedullary Nailing Systems) | REMARKS |
|---|---|---|---|
| 01 | Indications for use | Same intended use in New Device and Predicate device | Equivalent |
| 02 | Material | Same material used in New Device and Predicate device, however, Subject device is available in Stainless Steel type also. | Equivalent |
| 03 | Performance Standards | Same performance standards used in both New Device as well as predicate device | Equivalent |
| 04 | Sterilization | Same method of sterilization used in both New Device as well as Predicate device | Equivalent |
| 05 | Dimensional Verification | There are two differences in the geometry however, these do not affect the safety and do not raise any safety concerns over the predicate device. A detailed analysis is provided in Section-10 Executive summary. The performance test results however are at part indicating the performance equivalence. | Equivalent |

**Following is the summary of parameters in which the comparison has been verified:**
**Ga-mma Nail versus Predicate Device**

| S. No. | CHARACTERISTICS | PREDICATE DEVICE VERSUS NEW DEVICE (GPC Intramedullary Nailing Systems) | REMARKS |
|---|---|---|---|
| 01 | Indications for use | Same intended use in New Device and Predicate device | Equivalent |
| 02 | Material | Same material used in New Device and Predicate device | Equivalent |
| 03 | Performance Standards | Same performance standards used in both New Device as well as predicate device | Equivalent |
| 04 | Sterilization | Same method of sterilization used in both New Device as well as Predicate device | Equivalent |
| 05 | Dimensional Verification | The end cap in subject device has been provided with collar that prevents sharp edges at the proximal end of nail to avoid vascular trauma, and also giving additional strength and safety to the proximal end of the nail, however that does not lead to any safety concerns related to device performance. | Equivalent |

B 1) **Discussion on the non-clinical testing performed**
Following are the applicable product standards considered for non-clinical standards
A: Material Standards
B: Performance Standards

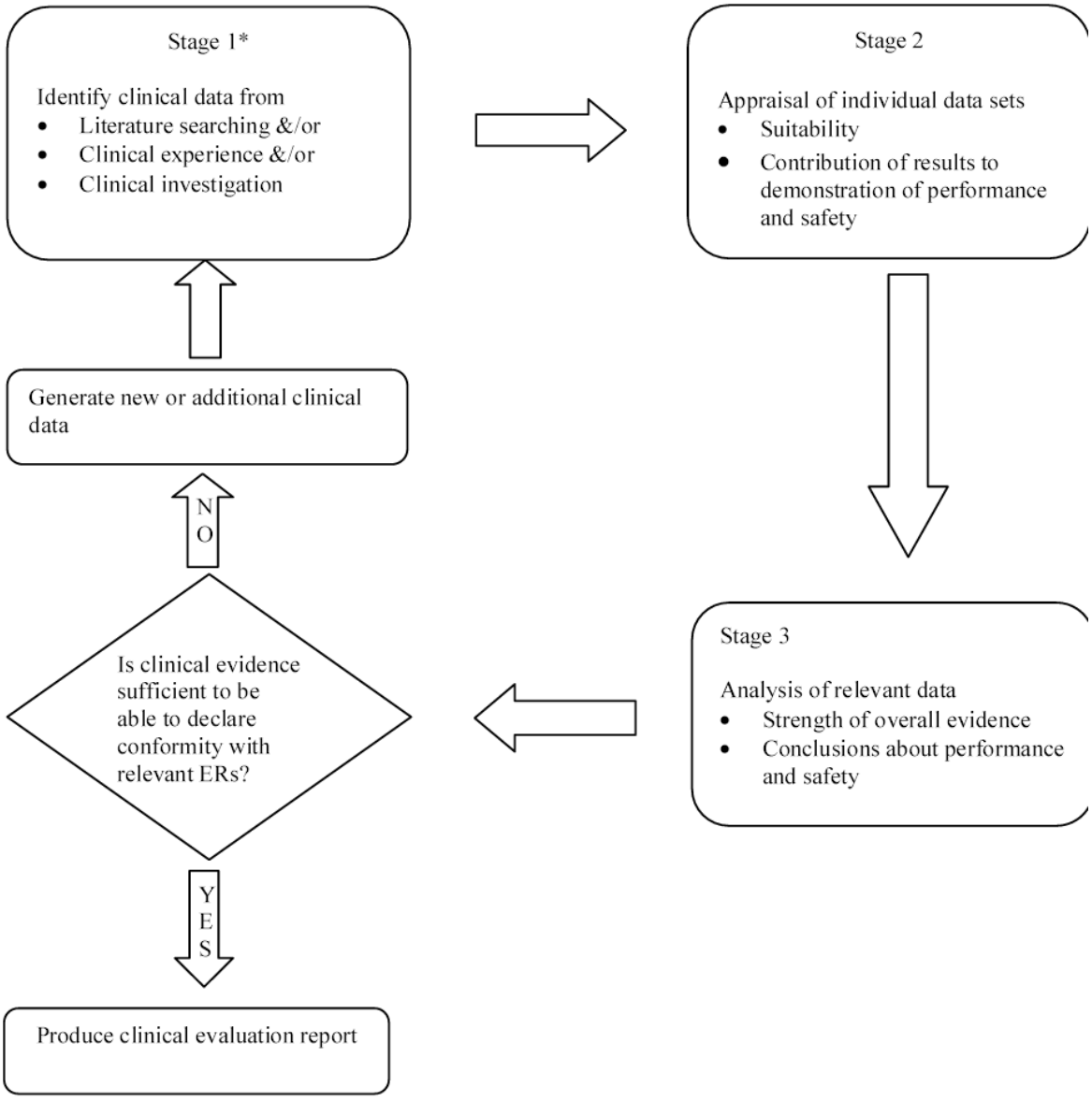
**A: Material Standards:** The material standards are the essential part to be complied to first, as it is the basis of manufacturing metallic surgical implants.
We have complied with two material standards

1. ASTM F 136: Standard specification for wrought Titanium-6Aluminium-4Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.
2. ASTM F 138: Standard Specification for Wrought 18 chromium-14Nickel-2.5Molybdenum stainless steel bar and wire for surgical implants.

**B: Performance Standards:**
We have verified the product compliance to these standards-ASTM F 1264 for Multi Angle Tibial Nail and ASTM F 384 for Ga-mma Nails and the relevant test results comparing the subject devices with predicate devices is given in section-10 executive summary.

**B 2)** Discussion on the clinical evaluation referenced and relied upon:
GPC Intramedullary nailing systems are of similar design and pattern as well as similar indications for use, similar technological characteristics to that of predicate devices. Following is the flow chart that has been considered for clinical evaluation / clinical equivalence

**Figure 1: Stages of clinical evaluation**




*Conformity to harmonized performance standards may be sufficient to demonstrate compliance to relevant Essential Requirements (ERs)

Based on the following aspects a literature survey and conclusion has been drawn and there is no need to have clinical evaluation done as the device is substantially equivalent to the predicate devices already in the US Market for more than 10 years.

**CONCLUSION BASED ON THE CLINICAL AND NON-CLINICAL TESTING DATA:**

From the available data, we at GPC demonstrate that GPC Intramedullary Nailing Systems are as safe, as effective and perform as same indications for use as that of already marketed predicate devices identified in A 3 of 510(k) summary.
Hence our devices can be considered safe and effective for their intended use.